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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,372	11/02/2001	Sojiro Shiokawa	Q64460	8305

7590 04/28/2005  
Sughrue Mion Zinn Macpeak & Seas  
2100 Pennsylvania Avenue N W Suite 800  
Washington, DC 20037-3213

EXAMINER
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COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/856,372

Applicant(s)

SHIOKAWA ET AL.

Examiner

Brenda L. Coleman

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Claims 1 and 18-21 are pending in the application.

This action is in response to applicants' amendment dated February 14, 2005.

Claim 21 has been amended and claims 22 and 23 have been canceled.

### *Response to Amendment*

Applicants' arguments filed February 14, 2005 have been fully considered with the following effect:

1. The applicants' amendments, arguments and filing of the Declaration under 37 C.F.R. § 1.132 are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of claims 1 and 18-23 over SATO et al., Journal of Medicinal Chemistry maintained in the last office action, which is hereby **withdrawn**.
2. The applicants' amendments, arguments and filing of the Declaration under 37 C.F.R. § 1.132 are sufficient to overcome the 35 U.S.C. § 103, obviousness rejection of claims 1 and 18-23 over SATO et al., EP 0 806 419 maintained in the last office action, which is hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled d), e), f) and g) maintained in the last office action, which are hereby **withdrawn**.
4. With regards to the obviousness-type double patenting rejection of claims 1 and 18-23 over U.S. Patent No. 6,037,342 and U.S. Patent Application No. 10/219,496 (now U.S. Patent No. 6,867,226) maintained in the last office action, the applicant's arguments have

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been fully considered but are not found persuasive. The applicant's stated that any analysis employed in an obviousness-type double patenting rejection must parallel the guidelines for analysis of a § 103 obviousness determination, including the evaluation of all objective evidence of nonobviousness. Therefore, in light of Dr. Sato's Declaration, Applicants respectfully request withdrawal of the obviousness-type double patenting rejections. However the scope of the claims in U.S. 6,037,342 and U.S. 6,867,226 are such that the R<sub>5</sub> variable has been limited to hydrogen, thus a showing of unexpected results over the methylated homopiperazine is not sufficient with respect to the obviousness-type double patenting rejections.

Claims 1 and 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,037,342, for reasons of record and stated above.

5. Claims 1 and 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,867,226, for reasons of record and stated above.

6. With regards to the obviousness-type double patenting rejection of claim 18 over U.S. Patent No. 6,552,057 in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that any analysis employed in an obviousness-type double patenting rejection must parallel the guidelines for analysis of a § 103 obviousness determination, including the evaluation of all objective evidence of nonobviousness. Therefore, in light of Dr. Sato's Declaration, Applicants respectfully request withdrawal of the obviousness-type double patenting rejections.


However the scope of the compound claims in U.S. 6,552,057 is such that the R<sub>5</sub> variable has been limited to hydrogen, thus a showing of unexpected results over the methylated homopiperazine is not sufficient with respect to the obviousness-type double patenting rejections.

Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,552,057, for reasons of record and stated above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Brenda L. Coleman  
Primary Examiner Art Unit 1624  
April 26, 2005